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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/727,511	12/04/2000	Keith L. Arnold	N1086-071	5552

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EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 07/16/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application N .

09/727,511

Applicant(s)

ARNOLD ET AL.

Examin r

David H Kruse

Art Unit

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-- The MAILING DATE of this communication appears n the cover sheet with the c rresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2003 .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 17-19 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 17-19 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____ .

DETAILED ACTION

1. The finality of the Office action mailed 21 March 2003 is herein withdrawn in view of the new rejections put forth below.
2. The Amendment filed 26 June 2003 has been entered.
3. Claims 1-11, 17-19 and 24 are pending in the instant application.
4. Those rejections not specifically addressed in this Office action are withdrawn in view of Applicant's arguments and/or amendments filed 26 June 2003.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

6. Claims 6, 17 and 18 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 6 is directed to a corn plant defined as comprising a gene conferring male sterility wherein the described inbred corn line is described as male fertile. Claims 17 and 18 are drawn to a method of using non-exemplified hybrids.

Applicant has only adequately described how to produce male sterile corn plants from the exemplified LH246 line by direct introduction of a transgene, Applicant does not adequately describe how to produce a cytoplasmic male-sterile LH246 line or male-sterile corn plant by crossing said LH246 line with another corn line comprising a

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transgene with a male-sterile conferring transgene. No guidance has been provided regarding the genetic or morphological characteristics of any of a multitude of breeding partners, or the resultant hybrid progeny required to practice the method of claim 17 and 18. Guidance has only been provided for a method of using the exemplified inbred cultivar in a process for producing an F1 hybrid.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to be in possession of the claimed invention at

the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

7. Claims 6, 17 and 18 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As directed to claim 6, Applicant has provided no working example of a male sterile corn plant defined as comprising a gene conferring male sterility. Applicant's teachings are prophetic as directed to making and using a male sterile corn line from inbred corn line LH246, and applicant does not teach what cytoplasmic male-sterile corn plants can be used to make a male sterile corn line from inbred corn line LH246. In addition the introduction of a transgene from a different corn line comprising a gene conferring male sterility has not been adequately taught or enabled in the instant specification.

As directed to claims 17 and 18, because Applicant has failed to adequately describe the genus of hybrid corn plants, one of whose parents is inbred LH246, as outlined above, Applicant has failed to enable the claimed method.

Hunsperger et al (1996, U.S. Patent 5,523,520), Kraft et al (2000, Theor. Appl. Genet. 101:323-326), and Eshed et al (1996, Genetics 143:1807-1817) teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a

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different plant, to confer a desired phenotype in said different plant. Hunsperger et al teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (see, e.g., column 3, lines 26-46). In particular, Hunsperger et al teach that a gene conferring miniature plant stature which has been identified and genetically stabilized in one cultivar of *Petunia hybrida*, a member of the Solanaceae, does not confer a miniature phenotype when introgressed into the genome of a variety of other *Petunia hybrida* cultivars (see, e.g., column 3, lines 40-41).

Kraft et al teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype-specific and loci-dependent in nature (see, e.g., page 323). Kraft et al teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is typically known about the plant breeding materials, which contributes to the unpredictability of the effect. Eshed et al teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (see, e.g., page 1815).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to make and use a corn plant produced from the exemplified LH246 comprising a gene

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conferring male sterility without using transgenic methods. In addition, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to make and use a myriad of hybrid corn plant^s, one of whose parents is inbred LH246 to practice the claimed method at claims 17 and 18. Segebart (U.S. Patent 5,367,109) teaches that the objective of commercial maize inbred line development programs is to develop new inbred lines that combine to produce high grain yields and superior agronomic performance in hybrid combinations (column 1, lines 40-43). Segebart also teaches that one of the largest plant breeding programs in the world does not have a sufficiently large breeding population to be able to rely upon "playing the numbers" to obtain successful research results (column 4, 1st paragraph). Hence, even the art teaches that trial and error experimentation is required to make and use hybrids of maize, and given the breadth of the claimed invention, it would have required undue experimentation to practice the method at claims 17 and 18 as broadly claimed.

The cancellation of claim 6 and the submission of the following proposed claims would obviate this rejection and the rejection under written description outlined above:

-- New claim 33. A method of producing a male sterile corn plant comprising transforming the corn plant of claim 2 with a nucleic acid molecule that confers male sterility.

New claim 34. A male-sterile corn plant produced by the method of claim 33. --

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8. Claims 1-11, 17-19 and 24 remain rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This rejection is repeated for the reason of record as set forth in the last Office action mailed 21 March 2003. Applicant's arguments filed 26 June 2003 have been fully considered but they are not persuasive.

Applicant argues that a deposit of seed of the claimed variety will be made with the ATCC in compliance with the rules[“] upon issuance of a Notice of Allowance in the case (page 3 of the Response). The Examiner responds that the actual deposition of seed for the purposes of enablement of the instant application is not the issue. As provided in 37 C.F.R. § 1.809(a) and (c),[“] The examiner shall determine pursuant to § 1.104 in each application for patent, application for reissue patent or reexamination proceeding if a deposit is needed, and if needed, if a deposit actually made is acceptable for patent purposes.[”] In the instant case, Applicant does not provide an adequate statement regarding the making of an enabling deposit by which the examiner can determine the acceptability for patent purposes of such a deposit.

Conclusion

9. This Office action is non-final.
10. No claims are allowed.
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (703) 308-0196.

David H. Kruse, Ph.D.
14 July 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180/163f

